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TO: Executive Addressed

FR: Mary Ann N. Cotton, Vice President

RE: Nine Steps to Understanding the Product Recall Process

Eventually every company with a product will be faced with a recall. Recalls, depending on the product's profile and reputation, the threat, and the nature of the problem, can become high-visibility nightmares for the unprepared company. Here are nine important steps to managing a recall:

1. A recall is essentially an action taken to remove a product that represents a threat to the consumer or violates a law. Recalls are usually voluntary unless the company refuses, which then often results in government seizure of the product.
2. Most government agencies have published guidelines in this area. One example is the U.S. Food and Drug Administration's *Recalls -- Guidelines on Policy, Procedures, and Industry Responsibilities*.
3. Communication plays a crucial role in recall success. How well the company communicates with the government, its customers, employees, and the media can significantly impact how the company is viewed over the long-term. Identify a corporate recall spokesperson and keep him or her up-to-date on the status of the recall. Take the time to prepare -- train and rehearse your people to manage a recall situation.
4. Develop a contingency plan and recall strategy. A contingency plan will provide the company with its own customized process to locate very specific information about the product, the problem, and how to locate the lots at issue.
5. Identify your recall team well in advance. The recall team oversees the recall and is responsible for its implementation. The team should consist of representatives from legal/regulatory, public affairs, marketing/distribution, customer service, and medical/quality assurance, along with a back-up for each.
6. Develop the corporate recall strategy now. Recall strategies typically consist of three elements: 1) the extent that information about a recall will be communicated; 2) a public warning; and 3) a check and balance system to ensure that a recall is effective.
7. Be prepared to supply accurate, useful information about the product recall and the process. Information made available often includes:

<ul style="list-style-type: none">o Identification of the product involvedo Reason for the removalo Evaluation of the risko Total amount of such products at issue	<ul style="list-style-type: none">o Distribution informationo Name and telephone number of the company official who should be contacted concerning the recall
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8. Companies are solely responsible for notifying the appropriate audiences. Communications should include information about the product, warning language to cease use of and distribution of the product, and instructions on how to handle the product being recalled. Communications can be sent in a number of ways (mailgrams, telegrams, first class mail) and should be marked, preferably in red type on the letter and envelope: "RECALL or CORRECTION." The letter and envelope should also be marked "URGENT."
9. Maintain clear, well-documented, organized records. Companies should prepare and maintain an organized, well thought out recall plan, use appropriate coding so that lot identification is efficient, and create and maintain product distribution records so that location of the product is relatively easy.

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